



CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED  
WITH THE UNITED STATES POSTAL SERVICE WITH SUFFICIENT  
POSTAGE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO:  
COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, ON

July 19, 2004

Diane H. Halata

Name of Person Mailing the Document

July 19, 2004

DATE

Attorney Docket No. P31731X1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Anders, *et al.*

Serial No.: 10/071,338

Group Art Unit No.: 1652

Filed: February 8, 2002

Examiner: Kathleen Kerr

For: Isolated 5R Clavams and Methods for Their Manufacture

Commissioner of Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Information Disclosure Statement Under 37 C.F.R. §1.97(c)

The attached list of citations is being submitted under the provisions of 37 C.F.R. §1.56 and §1.97 in order to comply with the duty of disclosure. Their inclusion herein, however, should not be construed as an admission that any particular cited reference is effective prior art or that it discloses or renders obvious any aspect of the claimed invention.

The references cited herein are listed on the enclosed PTO Form 1449.  
Copies of each are enclosed.

This statement is being filed under the provisions of 37 C.F.R. §1.97(c), before the mailing date of a Final Office action or before the mailing date of a Notice of Allowance, along with authorization to charge the \$180.00 fee specified in 37 C.F.R. §1.17(p) to the Deposit Account No. 19-2570.

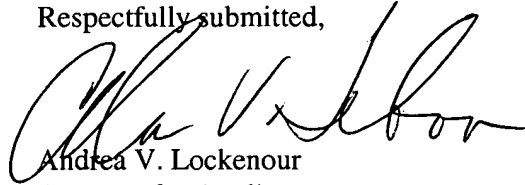
Please charge any additional fees under 37 C.F.R. §1.16 or §1.17 which may be required by this paper, or credit any overpayment, to the indicated Deposit Account.

07/26/2004 BABRAHA1 00000089 192570 10071338

01 FC:1806 180.00 DA

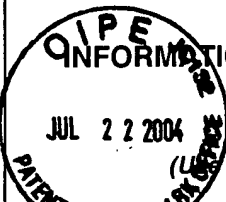
Serial No.: 10/071,338  
Group Art Unit No.: 1652

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Andrea V. Lockenour', written in a cursive style.

Andrea V. Lockenour  
Attorney for Applicants  
Registration No. 51,962

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-7568  
Facsimile (610) 270-5090  
N:\AVL\patapps\P31731\P31731X1C1\IDS2.doc

|   |  |                                 |                          |
|---|--|---------------------------------|--------------------------|
| Form PTO-1449   | U.S. Department of Commerce<br>Patent and Trademark Office | ATTY. DOCKET NO.<br>P31731X1C1  | SERIAL NO.<br>10/071,338 |
|  <b>INFORMATION DISCLOSURE STATEMENT<br/>BY APPLICANT</b><br><i>(Use several sheets if necessary)</i> |  | APPLICANT<br>Anders, et al.     |                          |
|   |  | FILING DATE<br>February 8, 2002 | GROUP<br>1652            |

**U.S. PATENT DOCUMENTS**

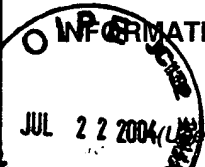
| Examiner<br>Initial | Document Number | Date    | Name           | Class | Subclass | Filing Date<br>If Appropriate |
|---------------------|-----------------|---------|----------------|-------|----------|-------------------------------|
|                     | 4,202,819       | 5/13/80 | Kellett et al. | 260   | 245.3    |                               |
|                     |                 |         |                |       |          |                               |
|                     |                 |         |                |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

|  | Document Number | Date    | Country       | Class | Subclass | Translation |    |
|--|-----------------|---------|---------------|-------|----------|-------------|----|
|  |                 |         |               |       |          | Yes         | No |
|  | 1 585 661       | 3/11/81 | Great Britain |       |          |             |    |
|  |                 |         |               |       |          |             |    |
|  |                 |         |               |       |          |             |    |

**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*

|   |   |
|---|---|
|   | Hodgson, J.E. et al., Gene, (1995) Vol. 166, pp. 49-55                              |
|   | Egan, L.A. et al., J. AM. Chem. Soc., (1997), Vol. 119, pp. 2348-55                 |
|   | Busby, R.W., J. Biological Chem., (1995), Vol. 270(9), pp. 4262-69                  |
|   | Brown, D. et al., J.C.S. Chem. Comm., (1979), pp. 282-3                             |
|   | Evans, R. H. et al., J. Antibiotics, (1983), Vol. 36(3), pp. 213-216                |
|   | Muller, J-C. et al, J. Antibiotics, (1983), Vol. 36(3), pp. 216-224                 |
|   | Marsh, E.N. et al., Biochemistry, (1992), Vol. 31, pp. 12648-57                     |
|   | King, H.D. et al., J. Antibiotics, (1986), Vol. 39(4), pp. 510-15                   |
|   | Janc, J.W. et al., J. Biological Chem., (1995), Vol. 270(10), pp. 5399-5404         |
|   | Iwata-Reuly, D. and C. A. Townsend, J. Am. Chem. Soc., (1992), Vol. 114, pp. 2762-3 |
|   | Paradkar, A. S. and S. E. Jensen, J. Bacteriology, (1995), Vol 177(5), pp. 1307-14  |
|   | Baldwin, J. E. et al., Tetrahedron Letters, (1994), Vol. 35(17), pp. 2783-6         |
| EXAMINER  | DATE CONSIDERED   |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |   |

|  |  |                                 |                          |
|--|--|---------------------------------|--------------------------|
| Form PTO-1449  | U.S. Department of Commerce<br>Patent and Trademark Office | ATTY. DOCKET NO.<br>P31731X1C1  | SERIAL NO.<br>10/071,338 |
|  <p><b>INFORMATION DISCLOSURE STATEMENT<br/>BY APPLICANT</b></p> <p><i>(Attach several sheets if necessary)</i></p> |  | APPLICANT<br>Anders, et al.     |                          |
|  |  | FILING DATE<br>February 8, 2002 | GROUP<br>1652            |

**U.S. PATENT DOCUMENTS**


| Examiner<br>Initial | Document Number | Date | Name | Class | Subclass | Filing Date<br>If Appropriate |
|---------------------|-----------------|------|------|-------|----------|-------------------------------|
|                     |                 |      |      |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

|  | Document Number | Date | Country        | Class | Subclass | Translation |    |
|--|-----------------|------|----------------|-------|----------|-------------|----|
|  |                 |      |                |       |          | Yes         | No |
|  | JP 53-104796    | 1978 | Kitano, et al. |       |          |             |    |
|  | ES 550549       | 1987 | C.M. Vidal     |       |          |             |    |

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

|   |   |
|---|---|
|   | A.L. Demain, "Biosynthesis and Regulation of Beta-Lactam Antibiotics", In: 50 Years of Penicillin Applications, History & Trends (1990).                  |
|   | Townsend, et al., J. Am. Chem. Soc., 107(4):1066-1068 (1985).   |
|   | Valentine, et al., J. Chem. Soc. Chem. Comm., 15:1210-1211 (1993).  |
|   | Janc, et al., Bioorg. Med. Chem. Lett., 3:2313-2316 (1993).   |
|   | Rohl, et al., Arch. Microbiol., 147:315-320 (1987).   |
|   | Aidoo, et al., Gene, 147:41-46 (1994).  |
|   | Sambrook, et al., Molecular Cloning: A Laboratory Manual, 2nd Edition. Cold Spring Harbor Laboratory, Cold Spring Harbor, NY (1989).                      |
|   | British Pharmacopoeia (1993); Addendum (1994) pp. 1362-1363.  |
|   | British Pharmacopoeia Official Monographs, USP 23 NF18 pp: 384-385 (1985).  |
|   | Hopwood, et al., Genetic Manipulation of Streptomyces. A Cloning Manual (1985).   |
|   | Stahl, et al., In: Nucleic Acid Techniques in Bacterial Systematics. Ed. E. Stackebrandt & M. Goodfellow. Toronto: John Wiley & Sons, pp. 204-248 (1991). |
|   | Doran, et al., J. Bacteriol., 172(9):4909-4918 (1990).  |
|   | Vieira, et al., Methods Enzymol., 153: 3-11 (1987).   |
|   | Sanger, et al., Proc. Natl. Acad. Sci. USA, 74: 5463-5467 (1977).   |
|   | Ward, et al., Mol. Gen. Genet. 203: 468-478 (1986).   |
|   | Pruess, et al., The Journal of Antibiotics, XXXVI(3): 208-212 (1983).   |
|   | Paradkar, et al., Journal of Bacteriology, 177: 1307-1314 (1995).   |
| EXAMINER  | DATE CONSIDERED   |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |   |

|   |  |                                 |                          |
|---|--|---------------------------------|--------------------------|
| Form PTO-1449   | U.S. Department of Commerce<br>Patent and Trademark Office | ATTY. DOCKET NO.<br>P31731X1C1  | SERIAL NO.<br>10/071,338 |
|  |  | APPLICANT<br>Anders, et al.     |                          |
|   |  | FILING DATE<br>February 8, 2002 | GROUP<br>1652            |

## U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|------------------|-----------------|------|------|-------|----------|----------------------------|
|                  |                 |      |      |       |          |                            |
|                  |                 |      |      |       |          |                            |
|                  |                 |      |      |       |          |                            |
|                  |                 |      |      |       |          |                            |

## FOREIGN PATENT DOCUMENTS

|  |  | Document Number | Date | Country | Class | Subclass | Translation |    |
|--|--|-----------------|------|---------|-------|----------|-------------|----|
|  |  |                 |      |         |       |          | Yes         | No |
|  |  |                 |      |         |       |          |             |    |
|  |  |                 |      |         |       |          |             |    |
|  |  |                 |      |         |       |          |             |    |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|          |  |   |
|----------|--|---|
|          |  | Bailey, et al., "Cloning a <i>Streptomyces clavuligerus</i> Genetic Locus Involved in Clavulanic Acid Biosynthesis". <i>Biotechnology</i> , September 1984.   |
|          |  | Jensen, et al., "Extending the $\beta$ -Lactam Biosynthetic Gene Cluster in <i>Streptomyces clavuligerus</i> ". <i>Industrial Microorganisms – Basic and Applied Molecular Genetics</i> , Chapter 22, pp. 169-176 (1993)  |
|          |  | Mosher, et al., "Genes Specific for the Biosynthesis of Clavam Metabolites Antipodal to Clavulanic Acid are Clustered with the Gene for Clavaminate Synthase 1 in <i>Streptomyces clavuligerus</i> ". <i>Antimicrobial Agents and Chemotherapy</i> , 43(5): 1215-1224 (1999). |
|          |  |   |
|          |  |   |
|          |  |   |
| EXAMINER |  | DATE CONSIDERED   |

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

n:\av1\patapps\p31731\p31731d1\pto 1449 form.doc